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09/940,419	08/29/2001	Timothy Bateman	0100/0134	5102

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,419

Applicant(s)

BATEMAN ET AL.

Examiner

Teena K Mitchell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 and 10-12 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Objections***

Claim 12 is objected to because of the following informalities: In line 6, "... said sheet..." lacks antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Rudolph et.al. (6,082,360).

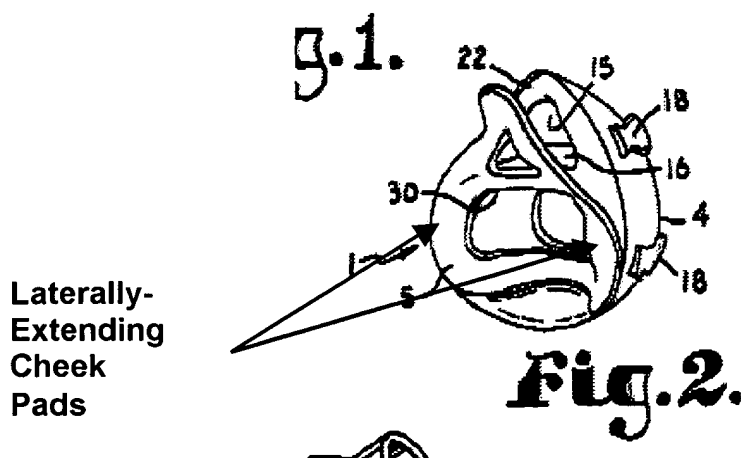
Rudolph in a ventilation device discloses:

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- a member (4) adapted to extend across the mouth and nose of a patient (Fig. 1);
- an opening (at 11) through said member in the region of the mouth;
- an adhesive surface (5) on the member (4) adapted to seal around the mouth and nose of the patient such that the nose is blocked and the mouth opens through said opening enabling ventilation via the mouth (Figs. 1-4).

With respect to claim 2, Rudolph discloses wherein said member includes a flexible sheet (5).

With respect to claim 3, Rudolph discloses wherein said sheet (5) has two laterally-extending cheeks pad (see illustration of Fig. 2 below).



With respect to claim 10, Rudolph discloses a flexible sheet (5) shaped to extend across the mouth and nose of a patient; a tubular fitting (11) having an opening extending through said sheet (Fig. 3) having an opening extending through said sheet in the region of the mouth such that the nose is blocked by adhesive contact of said sheet around the nose and the mouth opens through said opening enabling ventilation via the mouth.

With respect to claim 11, Rudolph discloses a removable vent tube inserted through said fitting (10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

**This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).**

**Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (6,082,360).**

Rudolph discloses a plate (4) having a central region and an outer flexible adhesive region (5), said outer adhesive region being shaped to extend across the mouth and nose of a patient (Figs. 1-4); a tubular fitting fixed with said central region (at 11) having an opening extending there through communicating with the region of the mouth such that the nose is blocked by adhesive contact of said sheet around the nose and the mouth opens through said tubular fitting enabling ventilation via the mouth.

The difference between Rudolph and claim 12 is a transparent region. Applicant has not disclosed that having a transparent region solves any stated problem or is for any particular purpose. Accordingly, the use of a transparent region is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Rudolph.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a transparent region because it would have provided a means to view a user's mouth area to ensure proper placement of the plate and to detect any obstructions.

**Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph et.al (6,082,360) in view of Smith (5,666,950).**

The difference between Rudolph and claim 6 is the adhesive being a hydrocolloid.

Smith in a stoma filter device teaches a hydrocolloid adhesive providing a composition, which absorbs significant quantities of moisture reducing skin maceration (Col. 5, lines 12-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adhesive of Rudolph to employ any well-known hydrocolloid doing so would have provided an adhesive which absorbs significant quantities of moisture reducing skin maceration including the hydrocolloid adhesive taught by Smith.

***Response to Arguments***

Applicant's arguments with respect to claims 1-6 and 10-12 have been considered but are moot in view of the new ground(s) of rejection.

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***Allowable Subject Matter***

Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

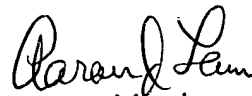
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Teena K Mitchell  
Examiner  
Art Unit 3743  
November 22, 2003



Aaron J. Lewis  
Primary Examiner